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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,914	07/25/2003	Anan Chuntharapai	50474/017002	2414

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EXAMINER	
SCHWADRON, RONALD B	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
11/26/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	10/626,914	3CHUNTHARAPAI ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,14,25,28,31,37,38 and 49-55* is/are pending in the application.

4a) Of the above claim(s) *49,50 and 52* is/are withdrawn from consideration.

5)☒ Claim(s) *28* is/are allowed.

6)☒ Claim(s) *1-4,14,31,37,38,51,53-55* is/are rejected.

7)☒ Claim(s) *25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/11/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant's election without traverse of human TACI receptor in the reply filed on 7/6/09 is acknowledged.

2. Claims 1-4,14,25,28,31,37,38,51,53-55 are under consideration.

3. In view of the papers filed 9/29/08, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by deleting Kyung Jin Kim and Minhong Yan, and by adding Dhaya Seshasayee.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-3,37,38,51,53,54 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed inventions.

The instant claims encompass an agonist antibody which binds a native human or mouse TACI receptor. The specification discloses an amino acid sequence encoding a single human TACI. It appears that a murine TACI was known in the art. The term "native TACI receptor" as defined in the specification, page 16 includes a potentially vast collection of unknown variants/alleles of murine or human TACI. The identity of the aforementioned unknown TACI variants/alleles is unpredictable. With the exception of the aforementioned mouse or human TACI of SEQ. ID. No 3, the skilled artisan cannot envision the detailed structure of the encompassed "agonist antibody which binds native TACI receptor" and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. In addition claim 3 discloses BCMA receptor and claim 1 recites BLyS wherein the same issues are present (specific known sequences in mouse and human, wherein the terms encompass unknown variants/species and wherein the identity of the unknown variants/mutants/species is unpredictable). Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. In the instant application, the amino acid itself or isolated protein is required. See Fiers v. Revel, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Lts., 18 USPQ2d 1016. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification(i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v.

Eli Lilly and Company (CAFC, July 1997) wherein is stated: "The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA." See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

Regarding applicants comments, the instant claims encompass an agonist antibody which binds a native human or mouse TACI receptor. The specification discloses an amino acid sequence encoding a single human TACI. It appears that a murine TACI was known in the art. The term "native TACI receptor" as defined in the specification, page 16 includes a potentially vast collection of unknown variants/alleles of murine or human TACI. The identity of the aforementioned unknown TACI variants/alleles is unpredictable. With the exception of the aforementioned mouse or human TACI of SEQ. ID. No 3, the skilled artisan cannot envision the detailed structure of the encompassed "agonist antibody which binds native TACI receptor" and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. In addition claim 3 discloses BCMA receptor and claim 1 recites BLyS wherein the same issues are present (specific known sequences in mouse and human, wherein the terms encompass unknown variants/species and wherein the identity of the unknown variants/mutants/species is unpredictable).

6. Claims 1-4,14,31,37,38,51,53-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
There is no support in the specification as originally filed for the recitation of "and activates NF-kB, and wherein the antibody does not inhibit a native sequence mouse or human BLyS binding to said TACI receptor" in the context recited in claim 1. Regarding applicants comments about cancelled claim 23, said claim is not drawn to an agonist antibody and does not disclose that the antibody activates NF-kB. Therefore, the disclosure is not commensurate with that of the claimed invention wherein the antibody is an agonist antibody activates NF-kB, and wherein the antibody does not inhibit a native sequence mouse or human BLyS binding to said TACI receptor. Regarding applicants comments about Examples 5-7 said Examples refer to three specific monoclonal antibodies with specific amino acid sequences which bind specific epitopes wherein the claims under consideration encompass any antibody with the functional properties recited in the claims or encompass antibodies with less the entire intact amino sequence of the antibodies disclosed in Examples 5-7.
There is no written description of the scope of the claimed inventions in the specification as originally filed (aka the claimed inventions constitute new matter).

7. The rejection of claim 5 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons elaborated in the previous Office Action is withdrawn in view of the cancellation of said claim.

8. Regarding the application of prior art, the 7B6.15.11 hybridoma/antibody is not disclosed in parent application 60/398530. Regarding the application of prior art, the antibody of claim 23 is not disclosed in parent application 60/398530. Regarding claim 1, the "agonist antibody" as per defined in the instant application encompasses antibodies with the properties of claim 23, whilst parent application 60/398530 does not include such antibodies in the definition of "agonist antibody". In addition, for the same reasons that the claimed inventions lack written description as per above, said claims are not entitled to priority to parent application 60/398530.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. The rejection of claims 1-5,14,23,25,28,31,37,55 under 35 U.S.C. 102(a) as being anticipated by Seshasayee et al. for the reasons elaborated in the previous Office action are withdrawn in view of the Seshasayee and Grewal declarations under 37 CFR 1.132 filed 9/29/08 and cancellation of claims that have been cancelled.

11. The rejection of claims 1,3,23,37,38,53-56 under 35 U.S.C. 102(b) as being anticipated by Ashkenazi et al. (WO 01/60397) as evidenced by Seshasayee et al. is withdrawn in view of the amended claims, cancellation of claims that have been cancelled and applicants arguments.

12. Claim 1-3,37,38,51,53-55 are rejected under 35 U.S.C. 102(e) as being anticipated by Kindsvogel (US 2007/0049735) as evidenced by Seshasayee et al. Applicants arguments have been considered and deemed not persuasive. However, the rejection as applying to claim 14 is withdrawn in view of applicants arguments.

Kindsvogel teaches humanized and murine monoclonal agonist antibodies which bind TACI without binding BCMA (see [0028], [0014], [0015], [0223], [0224]). Said antibodies inherently have the functional properties of claim 1 because said activation of said receptor causes the functional activity recited in claim 1 (see Seshasayee et al., page 283, first column). Said antibodies can be antibody fragments or antibodies

conjugated to a cytotoxic agent (see [0016]). Said antibodies can bind the peptide recited in claim 55 (see [0110] and SEQ. ID. 4).
The antibodies can be made recombinantly in prokaryotic (unglycosylated) or eukaryotic (glycosylated) hosts (see [0109]-[0122]). Kindsvogel et al. disclose that said antibodies do not bind other proteins (see [0063] (aka the antibodies would not bind BLyS) wherein said antibodies would therefore not bind BLyS and would not inhibit binding of BLyS to the TACI receptor.

Regarding applicants comments, Kindsvogel et al. disclose that said antibodies do not bind other proteins (see [0063] (aka the antibodies would not bind BLyS) wherein said antibodies would therefore not bind BLyS and would not inhibit binding of BLyS to the TACI receptor.

13. Claim 28 is allowed. Claim 25 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ron Schwadron/
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